UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION	:	**HON. ROBERT B. KUGLER**
	:	
	:	**Civil No. 1:15-md-2606 (RBK)(JS)**
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' MOTION TO SEAL DOCUMENTS

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I. PRELIMINARY STATEMENT

On September 2, 2015, Plaintiffs filed a Motion to Compel the Production of Documents, which contained thirty exhibits [DE No. 107]. Eleven of the thirty exhibits were not filed publicly on the Court's docket. The Motion presently before this Court is Defendants' Motion to Permanently Seal six of the eleven Exhibits that Plaintiffs did not file publicly, plus one document, Exhibit 6, which was filed publicly on the Court's docket. Specifically, Defendants seek to permanently seal Exhibits 6, 11, 13, 16,17, 21 and 22.

Defendants' Motion to Seal should be denied in its entirety for at least two reasons.

First, contrary to Defendants' representations about the documents at issue, none of the documents contain any personal patient information, trade secrets, proprietary information or sensitive commercial information. Indeed, even a cursory review of the Exhibits at issue demonstrate that these documents do not contain any information whatsoever that would identify, much less harm, any patient or put the Defendants at a commercial disadvantage.

Second**,** Defendants have not, and indeed cannot, meet the burden set forth in Local Rule 5.3(c)(2) for sealing documents. Specifically, Defendants have not established that there is a "legitimate private or public interest which would warrant" sealing the documents at issue, nor have Defendants shown that they would suffer "a clearly defined and serious injury" if their requested relief is not granted. Instead, Defendants' Motion merely makes unsubstantiated allegations of harm, which are unsupported by any specific examples or articulated reasoning. The mere fact that the information in the documents may be embarrassing to the Defendants, or evidence a lack of concern for patient safety, does not create a legal justification for sealing these documents and protecting them from public disclosure.

Finally it is significant to note, what this Court has often emphasized, that in this district "it is well-settled that merely because a document is designated 'confidential' pursuant to a Discovery Confidentiality Order does not necessarily mean that the document satisfies the criteria for sealing pursuant to Local Civil Rule 5.3." *See e.g., Horizon Pharma AG v. Watson Laboratories Inc.*, No. 13-5124, 2015 U.S. Dist. LEXIS 80852 (D.N.J. Feb. 24, 2015) (Schneider, Mag. J.); *Supernus Pharmaceuticals, Inc. v. Actavis, Inc.*, No. 13-4740, 2014 U.S. Dist. LEXIS 162054 (D.N.J. Nov. 18, 2014) (Schneider, Mag. J.). That is certainly the case here, where much of the information the Defendants seek to seal is publicly available pursuant to 21 CFR § 314.430(e).

II. STATEMENT OF FACTS AND PROCEDURAL HISTORY

On June 8, 2015, this Court entered the parties' Stipulated Discovery Protective Order [DE 46]. Pursuant to this Order information is deemed "Protected Information" and is not to be disclosed to the public when it contains:

> **Proprietary, trade secrets and/or highly sensitive commercial information**, and which is believed in good faith by the Producing party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or as being entitled to protection under the Federal Rules of Civil Procedure and the Local Rules of the District of New Jersey or other applicable case law, and/or as Ordered by the Court.

See Protective Order at ¶10 (*emphasis added*).

On September 2, 2015, Plaintiffs filed a Motion to Compel the Production of Documents, which contained thirty exhibits [DE No. 107]. Eleven of the thirty exhibits were not filed publicly on the Court's docket. Those eleven Exhibits are: Exhibits 11, 13, 16, 17, 18, 19, 20, 21, 22, 27, and 29. The Defendants marked nine of those Exhibits, as "Protected Information"

pursuant to the Stipulated Discovery Protective Order.[1] The Defendants also marked Exhibit 6, which contains three MedWatch Adverse Event Reports, as "Protected Information." However, Exhibit 6 was filed on the Court's docket because the Defendants had redacted those reports before they were produced to the Plaintiffs. Those redactions eliminated any and all patient identifying information, thus the confidential designation was unnecessary. Defendants implicitly recognized that the MedWatch reports should not be marked confidential since they did not assert that this exhibit should be sealed when they communicated their positions to Plaintiffs during the meet and confer process. *See* Letter from Susan Sharko Dated September 9 attached hereto as Exhibit A.

The Defendants are now claiming that Exhibit 6, along with six other Exhibits that Plaintiffs did not file publicly on the Court's docket, should be permanently sealed and move this Court to seal these seven documents. The seven documents at issue are: Exhibits 6, 11, 13, 16, 17, 21 and 22. However, none of these seven documents contain "Protected Information," and therefore should not be permanently sealed.

The chart below describes the contents of each of the exhibits at issue.

Exhibit	**Description**
6	Three MedWatch Adverse Event Reports. **All personal patient identifying information**, including names, addresses and phone numbers was **redacted** from these reports before they were produced to the Plaintiffs. Therefore, this Exhibit does not disclose any personal or private information about any individual. This type of information is publicly available pursuant to 21 CFR § 314.430(e).
11	A one-page email between Defendants' employees relaying the fact that the FDA requested a review of all cases of Celiac disease that the company received for Benicar. The email is a

[1] Two of the eleven Exhibits that were not filed publicly, Exhibits 27 and 29, were not designated as "Protected Information" by the Defendants. The parties agree that those documents could have been filed on the docket and should not be sealed. Defendants also admit that Exhibits 18,19 and 20 should not have been designated confidential and concede that these documents should not be sealed.

Exhibit	Description
	brief exchange that includes the number of celiac cases associated with Benicar and whether the tablets contain gluten. Aside from the discussion of whether the drug contains gluten, no other formulaic properties of the drug are discussed. Moreover, Benicar's formula and ingredient information is already in the public domain due to their patent dispute with Mylan. Additionally, this type of information is publicly available pursuant to 21 CFR § 314.430(e).
13	A one page executive summary of a case analysis report that was submitted to the FDA as part of the Benicar New Drug Application. This type of information is publicly available pursuant to 21 CFR § 314.430(e).
16	A company presentation relating to adverse events reported in the company's global database. This type of information is publicly available pursuant to 21 CFR § 314.430(e).
17	A company presentation regarding how to disseminate safety information.
21	An email exchange between Defendants and their licensing partners which discusses revisions to the Benicar monograph.
22	An email exchange between Defendants' staffers regarding revisions to wording on the French website and other labeling changes.

III. ARGUMENT

A. None of The Exhibits At Issue Contain Any Personal Patient Information, Trade Secrets, Or Proprietary Information And Therefore Should Not Be Permanently Sealed.

The Defendants' Brief in Support of their Motion to Seal woefully mischaracterizes the documents at issue. For example, on page 1 of their Brief Defendants state: "[o]ther exhibits contain confidential patient information which must remain confidential pursuant to Federal Regulation." *See* Defendants' Brief [DE 150-1] at p. 1. This is a blatant mischaracterization. Defendants do not direct this Court to a single exhibit that contains any identifying patient information whatsoever, nor can they, because no such document exists. To the contrary, no exhibit attached to Plaintiffs' September 2, 2015 Motion to Compel contains any patient information. Exhibit 6 which consists of three MedWatch Adverse Event Reports was produced to the Plaintiffs by the Defendant with all personal patient identifying information redacted,

including names, addresses and phone numbers. Therefore, Exhibit 6 does not disclose any personal or private information about any individual patient, nor do any of the other six exhibits at issue.

The Defendants go on to contend that Exhibits 6, 13, 16 and 17 contain "trade secrets." Once again Defendants do not specify the nature of such "trade secrets," or why they contend these exhibits contain "trade secrets." In truth, a review of exhibits 6,13, 16 and 17 reveal that there are no trade secrets whatsoever contained in these documents. A "trade secret" is generally defined as: information that "derives independent economic value from not being known to others who can obtain economic value from its disclosure or use and that is the subject of reasonable efforts to maintain its secrecy." *See* N.J. Stat. §56:15-2 (2105); *see also Diversified Indus., Inc. v. Vinyl Trends, Inc.*, No 13-6194, 2014 U.S. Dist. LEXIS 61131 at *22 (D. N.J. May 1, 2014); *Stryker v. Hi-Temo Speciality Metals, Inc.*, No 11-6384, 2013 U.S. Dist. LEXIS 145956 at *15-16 (D. N.J. Oct. 9, 2013). Here, the Defendants do not point to any information in these four exhibits that derive independent economic value from not being known to others or explain how any of its competitors can obtain economic value from disclosure of this information.

Moreover, while Defendants seem to argue that Exhibits 6, 13 and 16 should be sealed because adverse event information somehow constitutes proprietary trade secrets or sensitive commercial information, in reality such information is publicly available pursuant to 21 CFR §314.430(e). 21 CFR §314.430(e) provides that once a New Drug Application is approved, safety and efficacy information, <u>including adverse event reports</u> regarding that drug must be made "immediately available for public disclosure." Specifically, the regulation reads, in pertinent part:

> (e) After FDA sends an approval letter to the applicant, the following data and information in the application or abbreviated application are **immediately available for public disclosure**, unless the applicant shows that extraordinary circumstances exist. . . .
>
> ***
>
> (4) **Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information** after deletion of the following:
>
> > (i) Names and any information that would identify the person using the product.
> >
> > (ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.
>
> (6) A**n assay procedure or other analytical procedure**, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61.[2]
>
> (7) All correspondence and written summaries of oral discussions between FDA and the applicant relating to the application, under the provisions of Part 20.

See 21 CFR §314.430(e) (2015) (*emphasis added).*

[2] §20.61 provides that "data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." 21 CFR 20.61(c) (2015) Trade Secrets and commercial or financial information are defined in turn as follows:

> A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process. (b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

21 CFR 20.61(a) (b) (2015). As discussed in detail above, there is no information in any of the exhibits at issue which meet this definition of trade secrets or commercial or financial information, and Defendants have not offered any evidence to the contrary.

The information that Defendants claim constitute trade secrets or highly sensitive commercial information is precisely the type of information that the FDA must publicly disclose pursuant to 21 CFR §314.430(e)(4)(6) and (7). Specifically, Exhibit 6 is simply three MedWatch Adverse Event Reports, in which all personal patient identifying information, including names, addresses and phone numbers were redacted before they were produced to the Plaintiffs. Exhibit 13 is merely a one page executive summary of a case analysis report that was submitted to the FDA as part of the Benicar New Drug Application. Exhibit 16 is a company presentation relating to adverse events reported in the company's global database, which contains no patient identifying information.

Defendants next argue that Exhibits 11, 21, and 22 should be sealed because they "contain protected email communications between Defendants' employees which are not meant to be public." *See* Defendants Brief [DE150-1] at p. 6. However, Defendants point to no case law, nor can they, to support their argument that because an email communication was not meant to be made public at the time it was drafted, it is therefore "protected" and should be kept under seal. If this proposition had any merit, every internal email communication in every case would be deserving of protection from public disclosure. This would lead to absurd results. Here, Exhibits 11, 21 and 22 are simply email exchanges between Defendants' employees that do not reveal any trade secrets or proprietary information, and therefore there is no justification for filing them under seal.

Finally, Defendants claim that Exhibit 11 also contains product formulation and ingredients, and that this is "clearly highly confidential and trade secret information." As an initial matter, Defendants' claim is false. Exhibit 11 only discusses whether Benicar contains gluten, and not any other formulaic properties. Furthermore Benicar's formula and ingredient information is already in the public domain due to Defendants' patent dispute with Mylan

Pharmaceuticals. Indeed, publicly available briefs and court opinions in the patent litigation discuss Benciar's formula and ingredients in detail. *See* Plaintiffs Post-Trial Brief in *Daiichi Sanko Company v. Mylan Pharmaceuticals* attached hereto as Exhibit B and The Court's July 30, 2009 Opinion in *Daiichi Sanko Company v. Mylan Pharmaceuticals* attached hereto as Exhibit C. Finally Benicar's New Drug Application contains formulaic properties and is available online at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-286_Benicar.cfm

B. Defendants Have Not Met Their Burden Under Local Rule 5.3

1. The Applicable Standard

In this Circuit there is a strong and well-established principle that there is "a common law public right of access to judicial proceedings and records." *In re Cendant Corp.*, 260 F.3d 183, 192 (3d Cir. 2001), *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1995); *see also Horizon Pharma AG v. Watson Laboratories Inc.*, No. 13-5124, 2015 U.S. Dist. LEXIS 80852 at *2 (D.N.J. Feb. 24, 2015) (Schneider, Mag. J.); *Supernus Pharmaceuticals, Inc. v. Actavis, Inc.*, No. 13-4740, 2014 U.S. Dist. LEXIS 162054 at *2-3 (D.N.J. Nov. 18, 2014) (Schneider, Mag. J.); *Schatz-Bernstein v. Keystone Food Products, Inc..*, No. 08-3079, 2009 U.S. Dist. LEXIS 34700 at *3 (D.N.J. Apr. 17, 2009) (Schneider, Mag. J.). This principle arises from "the strong public interest in transparent judicial proceedings." *Opperman v. Allstate New Jersey Ins. Co.*, No. 07-1887, 2009 U.S. Dist. LEXIS 111733 at *10, (D.N.J. Nov. 13, 2009) (Schnieder, Mag. J.).

In light of this deeply entrenched principle, when a party files a motion to seal it must demonstrate that "good cause" exists for protection of the material at issue. *Securimetrics, Inc. v. Iridian Techs., Inc.*, C.A. No. 03-4394 (RBK), 2006 U.S. Dist. LEXIS 22297 at *7 (D.N.J. Mar. 30, 2006). Good cause exists when a party makes "a particularized showing that disclosure will cause a 'clearly defined and serious injury to the party seeking closure.'" *Id*. (citing *Pansy v.*

Borough of Stroudsburg, 23 F.3d 772, 786 (3d Cir. 1994)). The particular requirements that must be met before a document will be sealed are set forth in Local Civil Rule. 5.3(c)(2). That Rule requires that a motion to seal describe: (a) the nature of the materials or proceedings at issue; (b) the legitimate private or public interest which warrants the relief sought; (c) the clearly defined and serious injury that would result if the relief sought is not granted; and (d) why a less restrictive alternative to the relief sought is not available. L. Civ. R. 5.3(c).

This rule must be strictly applied and this Court has often repeated that "general and conclusory statements [are] antithetical to the strict requirements in L.Civ. R. 5.3 (c)(2)." *See Surpernus Pharmaceuticals*, 2014 U.S. Dist. LEXIS 162054 at *7; *see also Opperman v. Allstate New Jersey Ins. Co.*, No. 07-1887, 2009 U.S. Dist. LEXIS 111733 at *33-34, (D.N.J. Nov. 13, 2009) (denying motion to seal and stating "Allstate has not overcome the strong public interest in transparent judicial proceedings by its mere generalized assertions (even if made by affidavit) that the materials are confidential and proprietary"); *O'Brien v. BioBanc USA*, No. 09-2289, 2010 U.S. Dist. LEXIS 72599 at *10-12, (D.N.J. July 19, 2010) (despite the fact that the document at issue was covered by a confidentiality agreement, request to seal denied where plaintiff merely provided a general cursory summary of the harms that would result from disclosure).

Indeed, with regard to requirement (c), the "clearly defined and serious injury" requirement, Courts in this Circuit have made clear that "broad allegations of harm, unsubstantiated by specific examples or articulated reasoning do not support a good cause showing." *See Pansy*, 23F.3d at 786; *see also Supernus Pharmaceuticals*, 2014 U.S. Dist. LEXIS 162054 at *7; *Locascio v. Balicki*, No. 07-4834, 2011 U.S. Dist. LEXIS 66679 (D.N.J. June 22, 2011).

2. Defendants Have Failed To Meet Their Burden With Regard to Requirements (b) and (c) Of Rule 5.3.

As set forth above, Rule 5.3(c)(2)(b) requires a litigant to demonstrate there is a legitimate private or public interest which warrants sealing the documents at issue. Here, Defendants fail to make this showing. Instead they offer nothing more than general and conclusory statements to support their claim that they have a legitimate interest in the sealing of these documents. Specifically, the Defendants identify the following two interests in support of their claims of that the Exhibits should be sealed: (1) "there is an expectation of confidentiality and privacy in all internal email communications among company employees"; and (2) "Defendants have a legitimate interest in protecting its sensitive and highly confidential proprietary information." *See* Defendants' Brief [DE 150-1] at p.8. These conclusory arguments do not meet the strict requirement of Rule 5.3(c)(2)(b). Indeed as discussed above, if Defendants' first argument were accepted than every internal email communication in every case would be deserving of protection from public filing. This would obviously lead to absurd results and frustrate the purpose behind Rule 5.3(c)(2).

Furthermore, Defendants' second argument—that they have a "legitimate interest in protecting their sensitive and highly confidential proprietary information"—is entirely circular. Defendants do not explain in any manner how or why any of the information in any particular exhibit is "sensitive" or "proprietary." Merely saying a document is "highly confidential" does not make it so. As this Court has often repeated, "it is well-settled that merely because a document is designated 'confidential' pursuant to a Discovery Confidentiality Order does not necessarily mean that the document satisfies the criteria for sealing pursuant to Local Civil Rule 5.3." *See e.g.*, *Horizon*, 2015 U.S. Dist. LEXIS 80852 at *3; *Supernus Pharmaceuticals*, 2014 U.S. Dist. LEXIS 162054 at *2.

Finally, Defendants have not come close to meeting the requirement set forth in Rule 5.3(c)(2)(c). The only harm Defendants point to is the generalized harm that: (1) "competing pharmaceutical companies will be able to review and evaluate these documents," and (2) "should this information be taken out of context, it may lead to unnecessary alarm to the patient community." *See* Defendants' Brief [DE 150-1] at p.9. These claims fall woefully short of articulating "a clearly defined and serious injury." These general assertions of harm are unsupported by any evidence, specific examples or articulated reasons. They are nothing more than cursory and conclusory arguments. Such unsupported assertions are not enough to meet the strict standards of Rule 5.3(c)(2) to which this District closely adheres.

For these reasons, Defendants' Motion to Seal should be denied in its entirety.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court deny Defendants' Motion to Seal in its entirety.

Dated: October 19, 2015

Respectfully submitted,

/s/Christopher L. Coffin
Christopher L. Coffin, Esquire
PENDLEY, BAUDIN & COFFIN, L.L.P.
1515 Poydras Street, Suite 1400
New Orleans, Louisiana 70112
Phone: (504) 355-0086
Fax: (504) 523-0699
Email: ccoffin@pbclawfirm.com

/s/ Richard M. Golomb
Richard M. Golomb, Esquire
GOLOMB & HONIK, P.C
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (215) 985-9177
Fax: (215) 985-4169
Email: rgolomb@golombhonik.com

/s/Adam M. Slater
Adam M. Slater, Esquire
MAIZIE SLATER KATZ & FREEMAN, LLC
103 EISENHOWER PARKWAY
Roseland, New Jersey 07068
Phone: (973) 228-9898
Fax: (973) 228-0303
Email: aslater@mskf.net

CERTIFICATE OF SERVICE

I Richard M. Golomb, Esquire, hereby certify that on this **19th** day of **October 2015**, I caused a true and correct copy of thee foregoing **Plaintiffs' Opposition to Defendants' Motion to Seal Documents** to be filed and served on all counsel of record via the Court's CM/ECF filing system and as indicated below to the following:

VIA HAND DELIVERY
The Honorable Robert B. Kugler
USDC FOR THE DISTRICT OF NEW JERSEY
Mitchell H. Cohen Building
& U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

VIA FEDERAL EXPRESS
Susan M. Sharko, Esquire
DRINKER, BIDDLE & REATH, LLP
600 Campus Drive
Florham Park, NJ 07932

DATED: October 19, 2015

/s/ *Richard M. Golomb*
Richard M. Golomb, Esquire